IBM Healthcare & Life Sciences

# IT Architectures and Solutions for Imaging Biomarkers

NIST “Imaging as a Biomarker” Workshop
Gaithersburg, MD, 14-15 September 2006

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# AGENDA

- **Context: Bio-Medical Imaging and Information Based Medicine**
- **Challenges in Pharma R&D Imaging Data Management**
- **The need for Standards (versus Harmonization)**
- **Challenges for developing and deploying standards**
- **IBM's Role**
- **Role of other Stakeholders**


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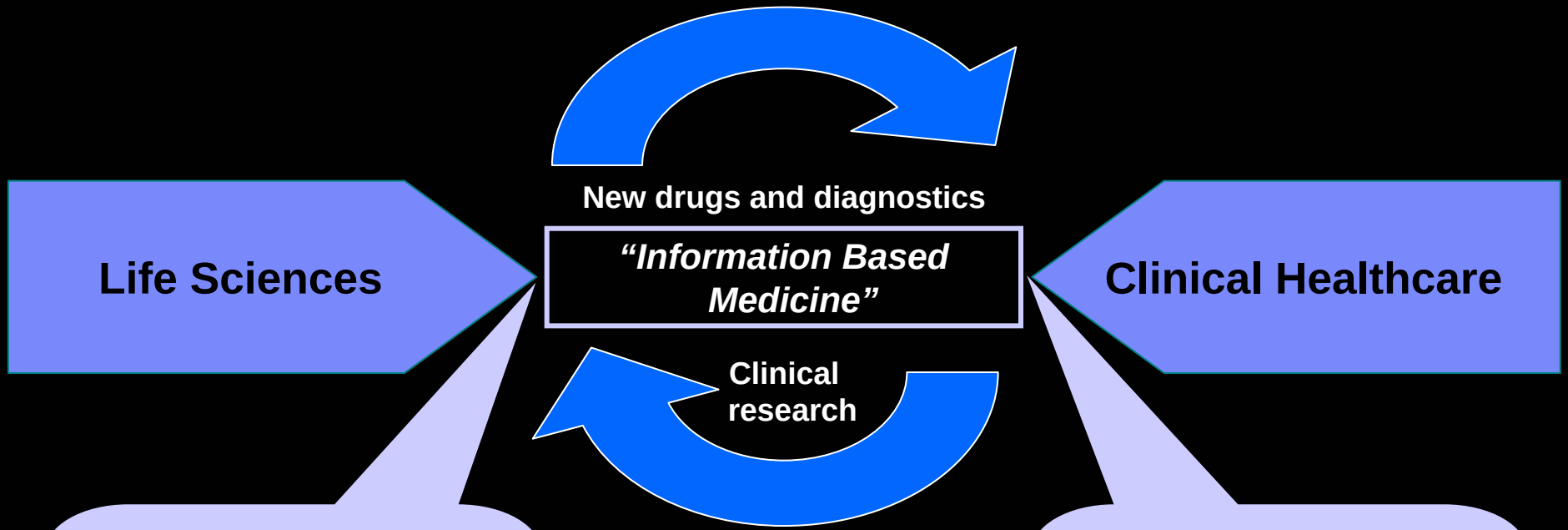
# Information Based Medicine(*): Innovation in Patient Care




1. Molecular level understanding of disease
2. Development of targeted drugs based on genomic insights

3. Delivery of personalized treatments based upon medical history and genetic predispositions
4. Predictive Medicine

*(*) Approach that transforms existing medical and pharmaceutical practices with actionable knowledge generated from the integration of clinical & biomedical data*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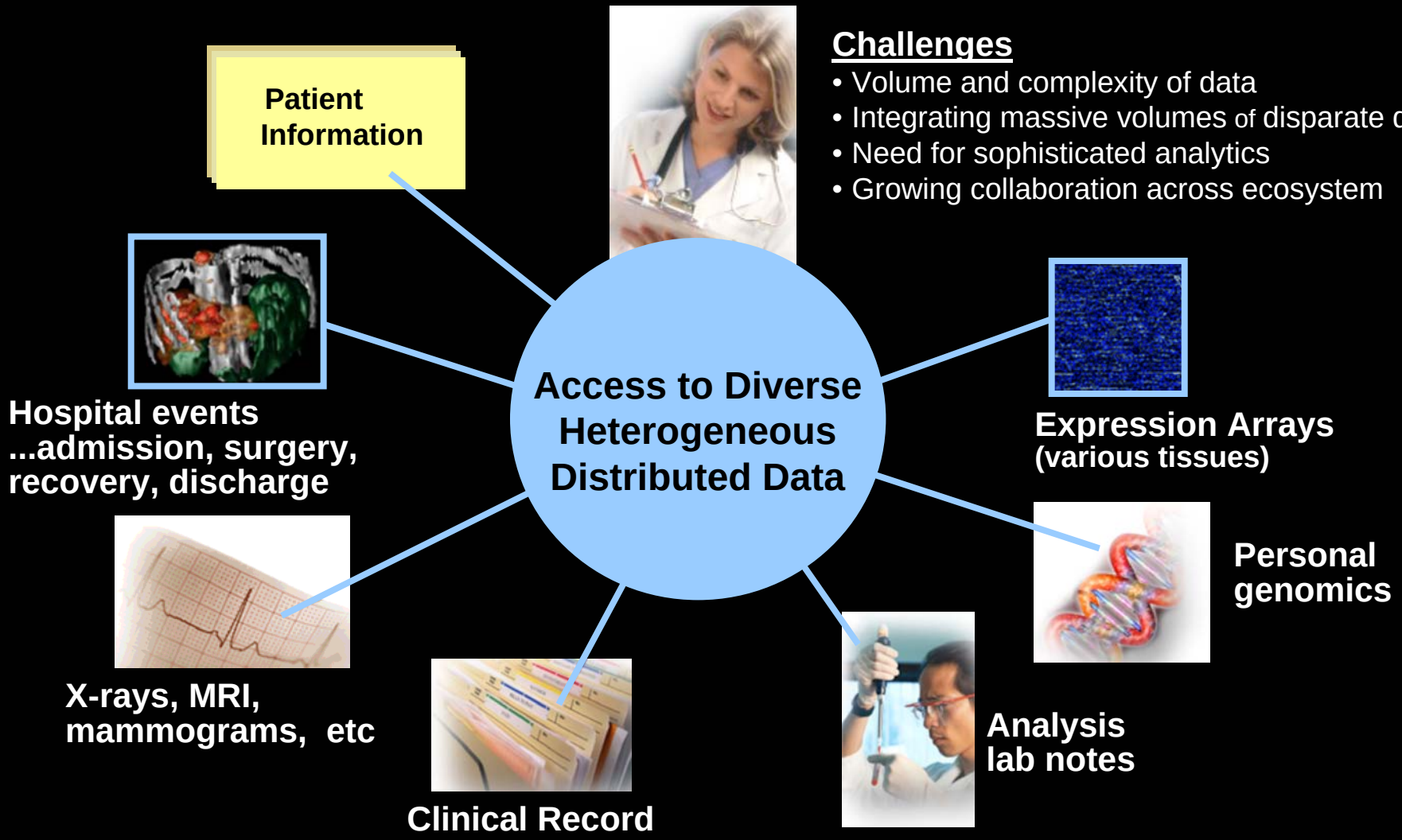
# Information Based Medicine requires access to diverse, integrated information





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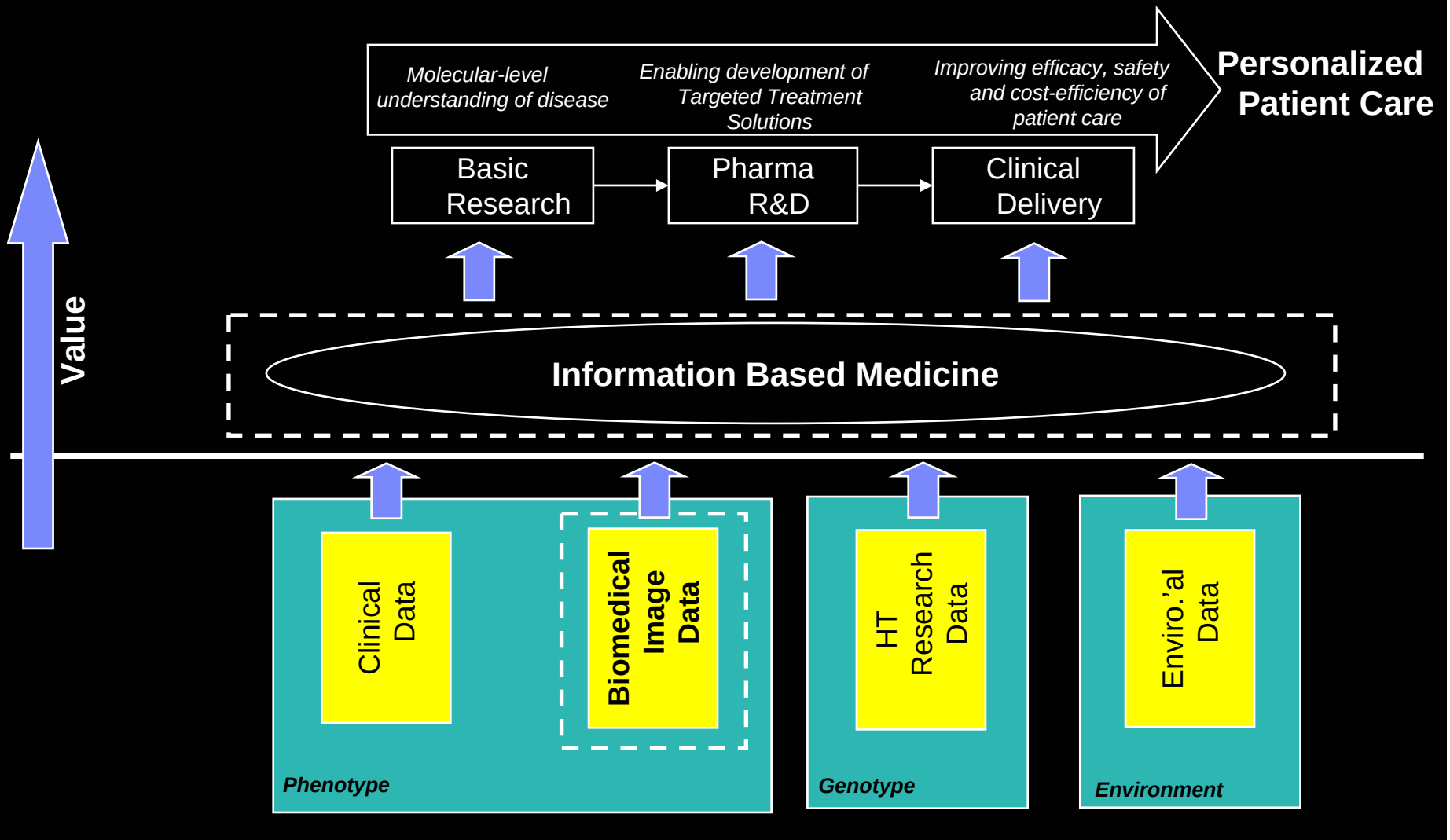
# Biomedical Imaging Data must be integrated with Clinical, Research and Environmental Data to enable the desired Transformation of Healthcare towards "Personalized Medicine"



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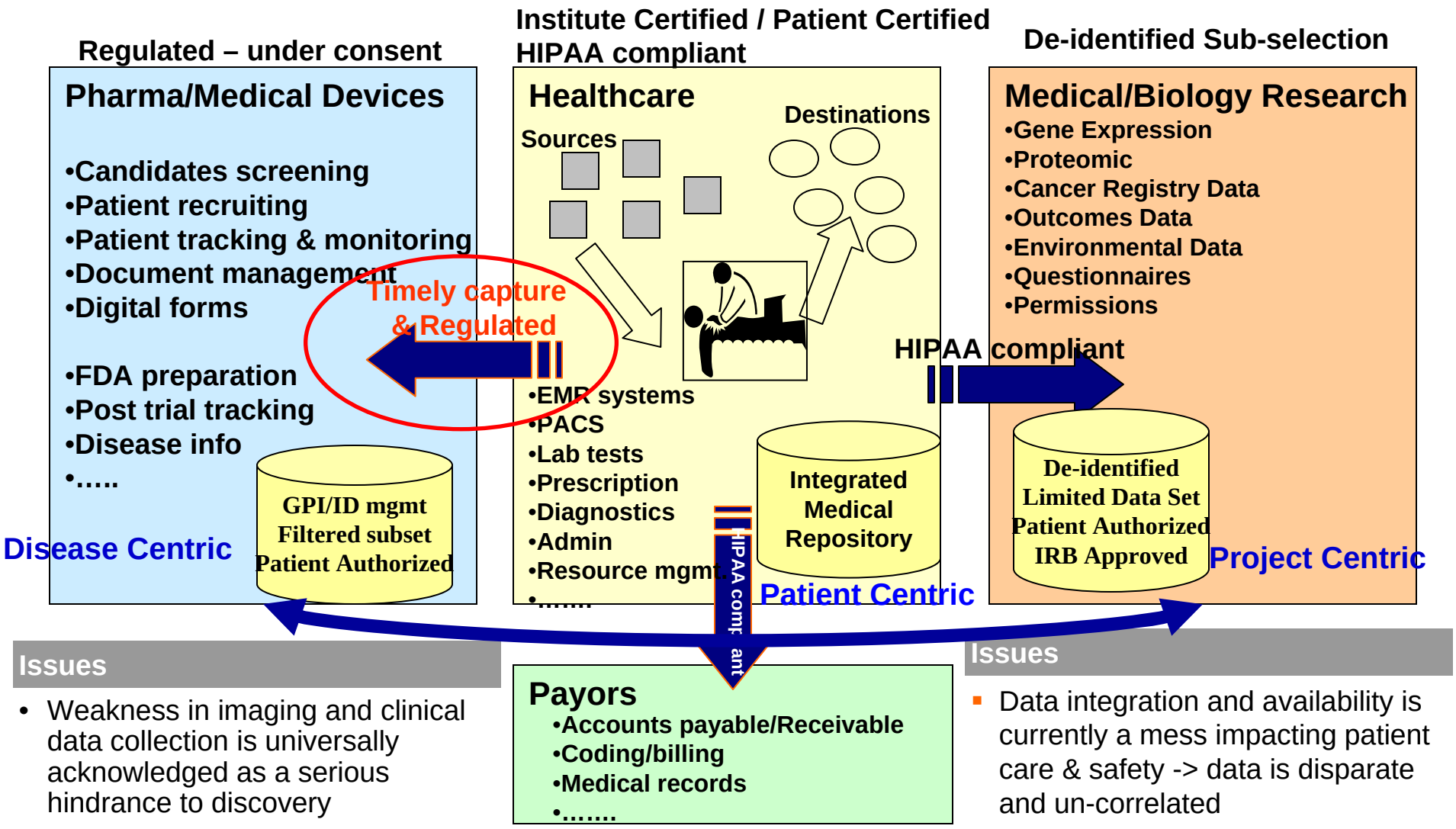
# Patient Centric Integrated Repositories – A World of Convergence




**Issues**

- Weakness in imaging and clinical data collection is universally acknowledged as a serious hindrance to discovery

**Issues**

- Data integration and availability is currently a mess impacting patient care & safety -> data is disparate and un-correlated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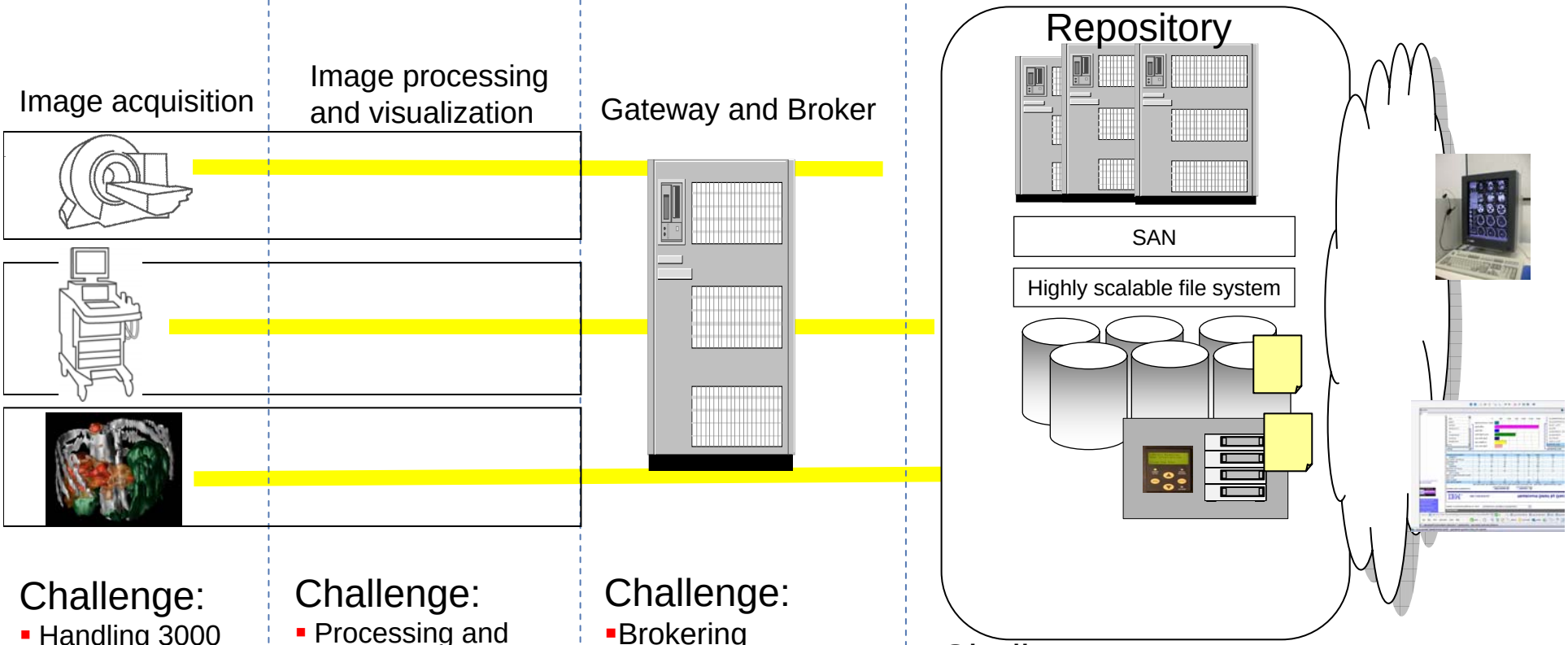
# IT in Support of Biomedical and Molecular Imaging




## Challenge:
- Handling 3000 images per scan
- Processing power
- IO bandwidth
- Network bandwidth

## Challenge:
- Processing and methods for image visualization and quantitative analysis
- 3D reconstruction
- Require to

## Challenge:
- Brokering
- Standards support
- Transformations
- Image distribution
- Transfer techniques
- Large objects transmission

## Challenge:
- Large data and storage mgmt.
- Very large file systems
- Standard, controlled and regulated access

- Heterogeneous Mining tools
- Network bandwidth
- Large Objects
- Data enrichment using biomarkers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# Image Management in Drug Discovery and Development

## Business Objectives

- Improve productivity in image submission, retrieval, analysis and results publication
- Reduce image management cycle time
- Improve image traceability
- Minimize errors
- Improve accuracy & validity
- Increased availability of data sharing
- Enable future submissions to FDA

## Technology Objectives

- Improve support of image analysis
- Reduce deployment and integration times
- Provide single platform for discovery and clinical trial image handling

## The IT Solution should address

- Controlled access & management of images
- Parent/child linkages
- Data extraction and association
- Full audit trail and traceability
- Open for integration with multiple image viewers and applications
- Integrated workflow
- Data enrichment using analytical tools
- Image versioning for updates
- Annotation and comments linked to images
- Biomarkers and surrogates stored and linked to the images


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# The need for Standards in Imaging Data Acquisition

- Adapters for Image Capture
  - Normalization to DICOM version 3.0
  - Converters from different formats
  - Data and metadata for reporting & workflow
  - Support for data cleansing, GPI, compression, privacy,
- Adapters for HL7 2.0
  - Demographic and clinical data
  - CDA conversion utility
- Collaboration services
  - HL7 for demographic and clinical data
- IHE to bind both protocols


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# IHE – Integrating the Healthcare Enterprise

- IHE drives the adoption of standards to address specific clinical needs by creating a framework for passing vital health information seamlessly across the entire healthcare enterprise
  - From application to application, system to system and setting to setting

- IHE currently provides the following frameworks:
  - Radiology Technical Framework
  - Laboratory Technical Framework
  - IT Infrastructure Technical Framework
  - Patient Care Coordination Technical Framework
  - Cardiology Technical Framework
- http://www.ihe.net


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# The need for Standards in Imaging Data Management

- Integration with the information systems through well defined protocols and standards
- DICOM for radiology/cardiology data
- HL7 for demographic and clinical data
- IHE to bind both protocols
- When standards are missing or fall short, through well defined and open interfaces
  - For scanned documents
  - For emerging modalities and data types such as proteomics, genomics
  - For custom integration needs
- Must enable to plug-in components from others, either commercial, academic modules, or open source


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# Web Based Access

- Portal-based interface
  - Personalized interface based on user role
- Query and browse stored data
  - Basic & Advanced Searches
  - Search for Related Objects
  - Saved Search
  - Full Text
- Display content – Attributes, Imagery
- Access from anywhere
- Efficient
  - Scale and compress data on the server to facilitate access over low-bandwidth (remote or wireless) connections


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# Storage Management

- Policy-driven retention and storage based on:
  - Recency
  - Frequency
  - Latency
  - Locality
- Integration between repository and storage infrastructure
  - Based on repository policies
  - Based on protocol rules
- Context based policies
  - Based on understanding of the metadata – modality type, patient age, diagnosis, radiologist
  - Based on enriched data which is added during the image processing – biomarkers, nominated images, ….


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# Regulatory Compliance

- Full audit trail
  - Event
  - User
  - Date/time
- Electronic signature
- Role-based security
- Controlled import/provisioning
- Tracking and Reporting
  - Image Status
  - Workflow Tracking
- Example
  - Using GE Centricity™ to generate additional data and store in repository under controlled process


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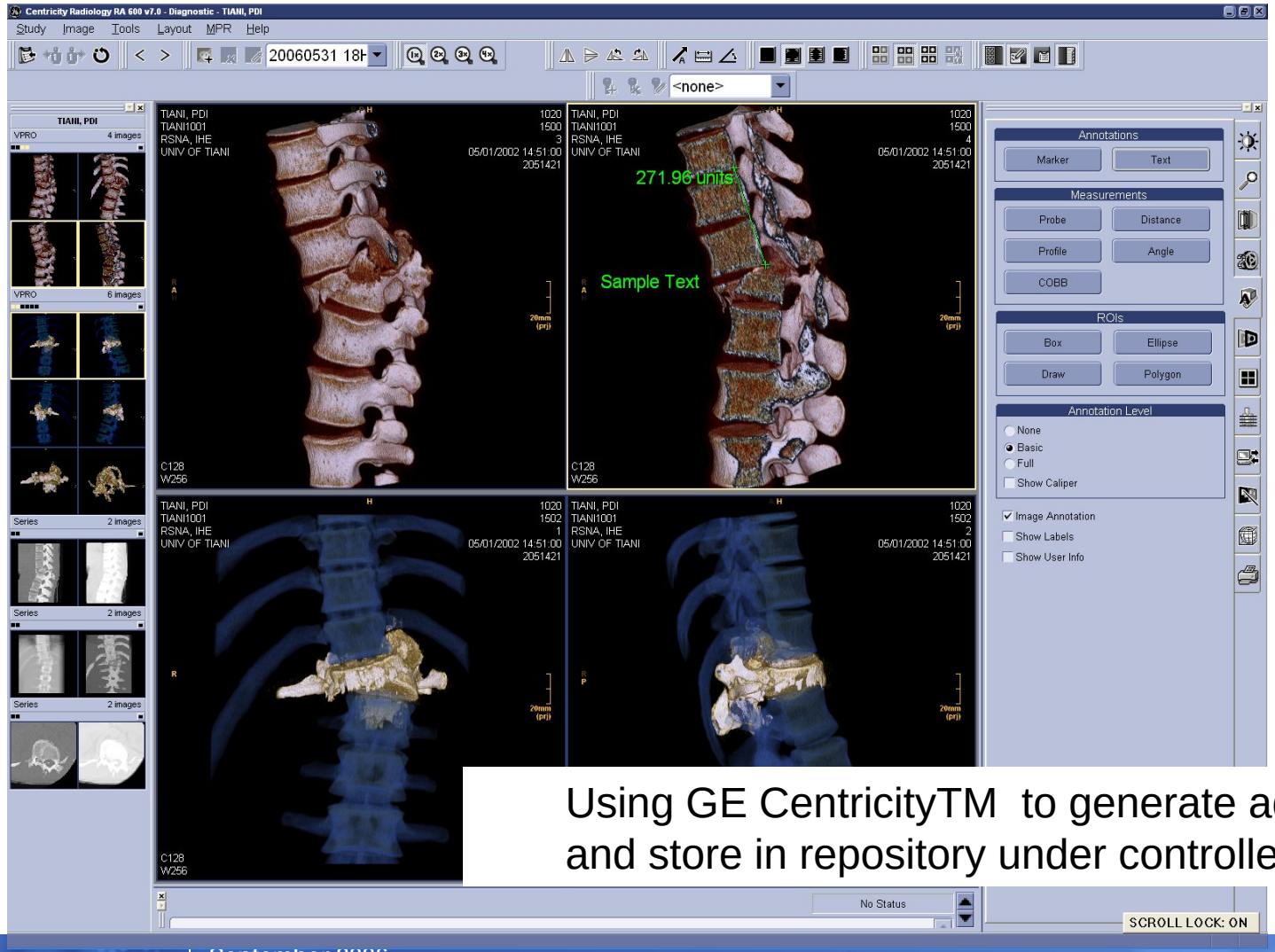
# Analysis performed by Researcher using Centricity™ – overlays created




Using GE CentricityTM to generate additional data and store in repository under controlled process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# Creating innovative and validated methods ...

**"A new product development toolkit (...) is urgently needed to improve predictability and efficiency along the critical path"**

- Opportunity: Imaging technologies, such as molecular imaging tools in neuropsychiatric diseases or as measures of drug absorption and distribution, may provide powerful insights into the distribution, binding, and other biological effects of pharmaceuticals, but their predictive value needs further study and evaluation. New imaging technologies will ultimately contribute important biomarkers and surrogate endpoints, but how soon these new tools will be available for use will depend on the effort invested in developing them specifically for this purpose.

**Source: Challenge and Opportunity on the Critical Path in New Medical Products. FDA, March 2004**


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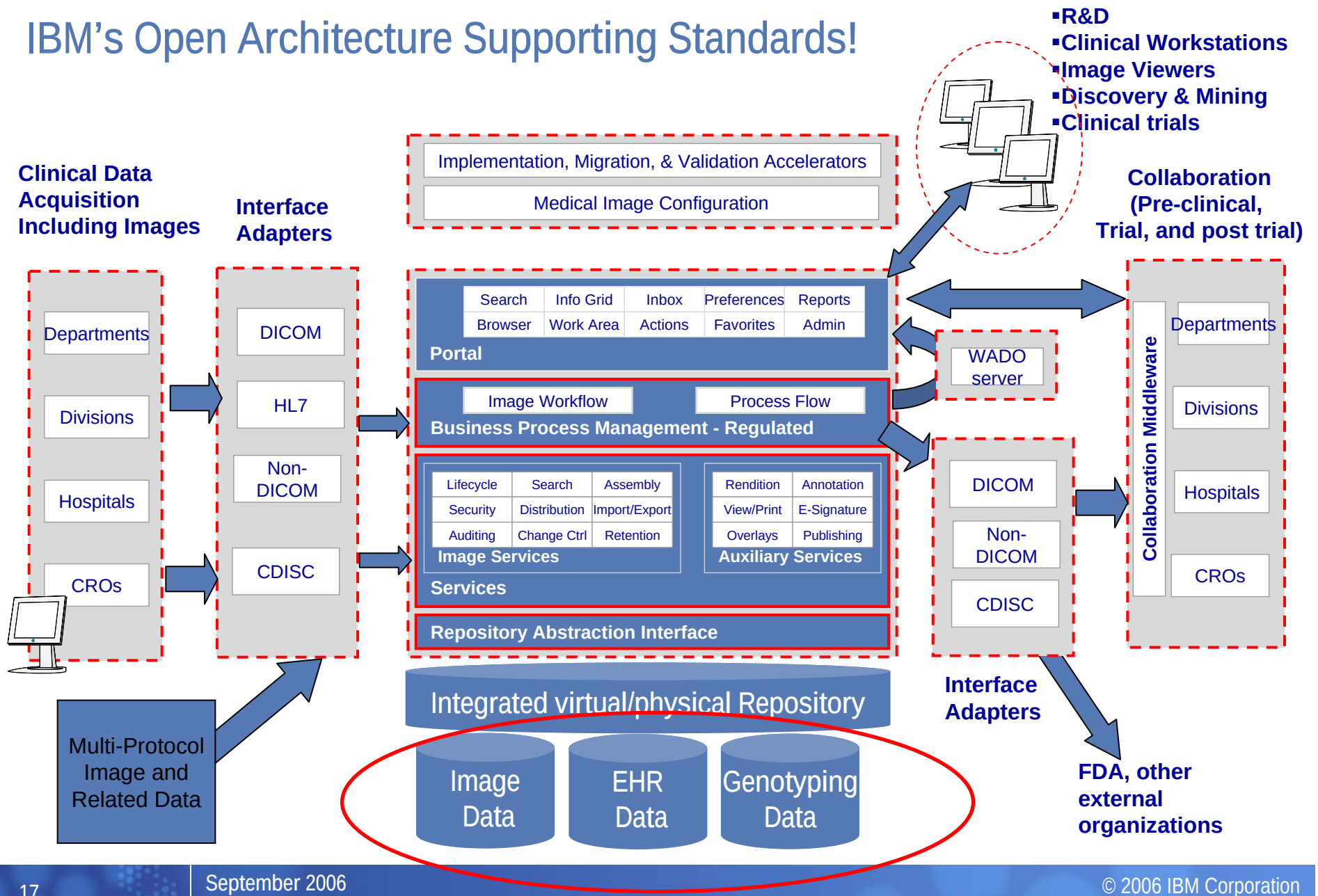
# IBM's Open Architecture Supporting Standards!





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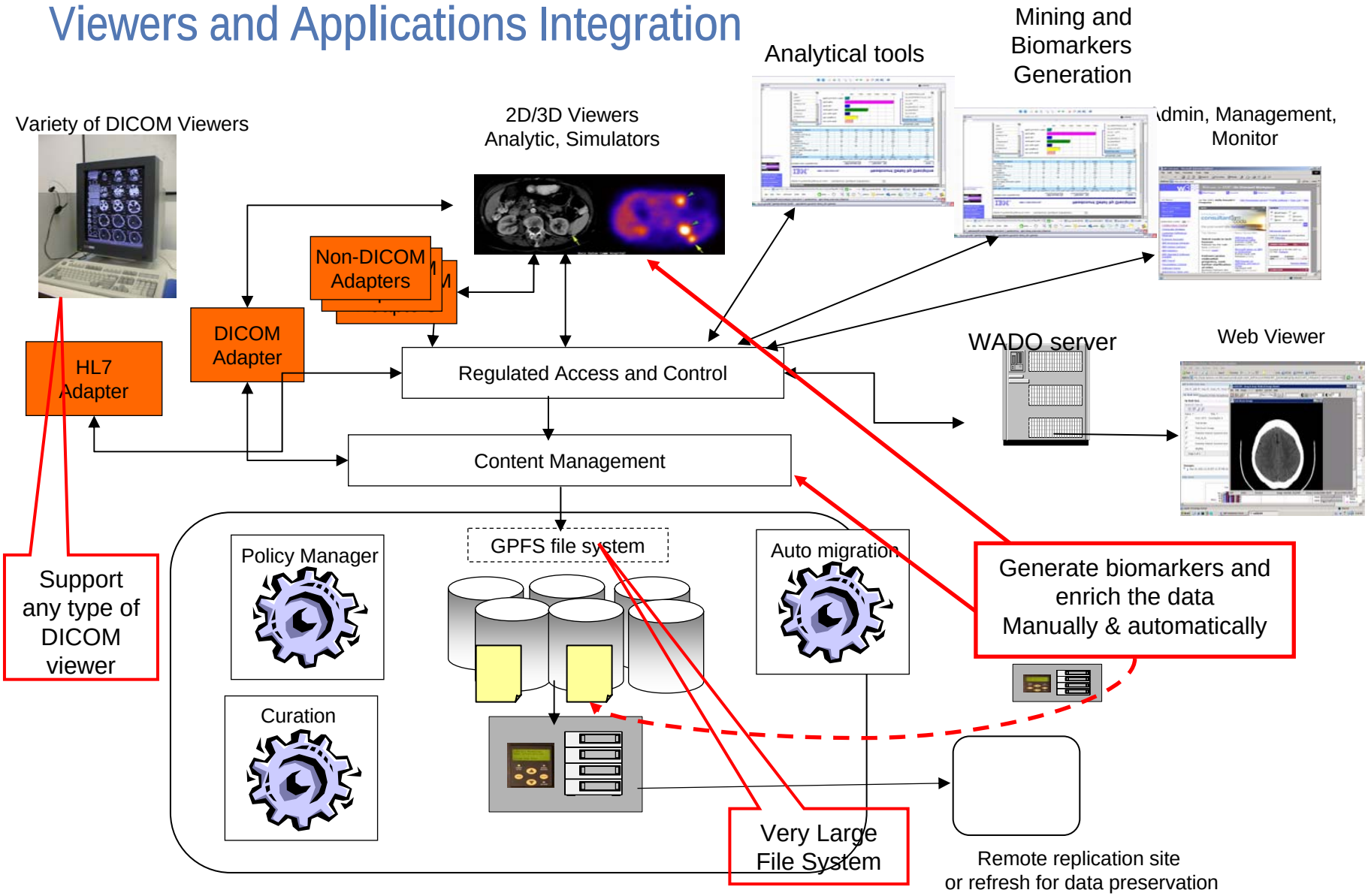
# Viewers and Applications Integration





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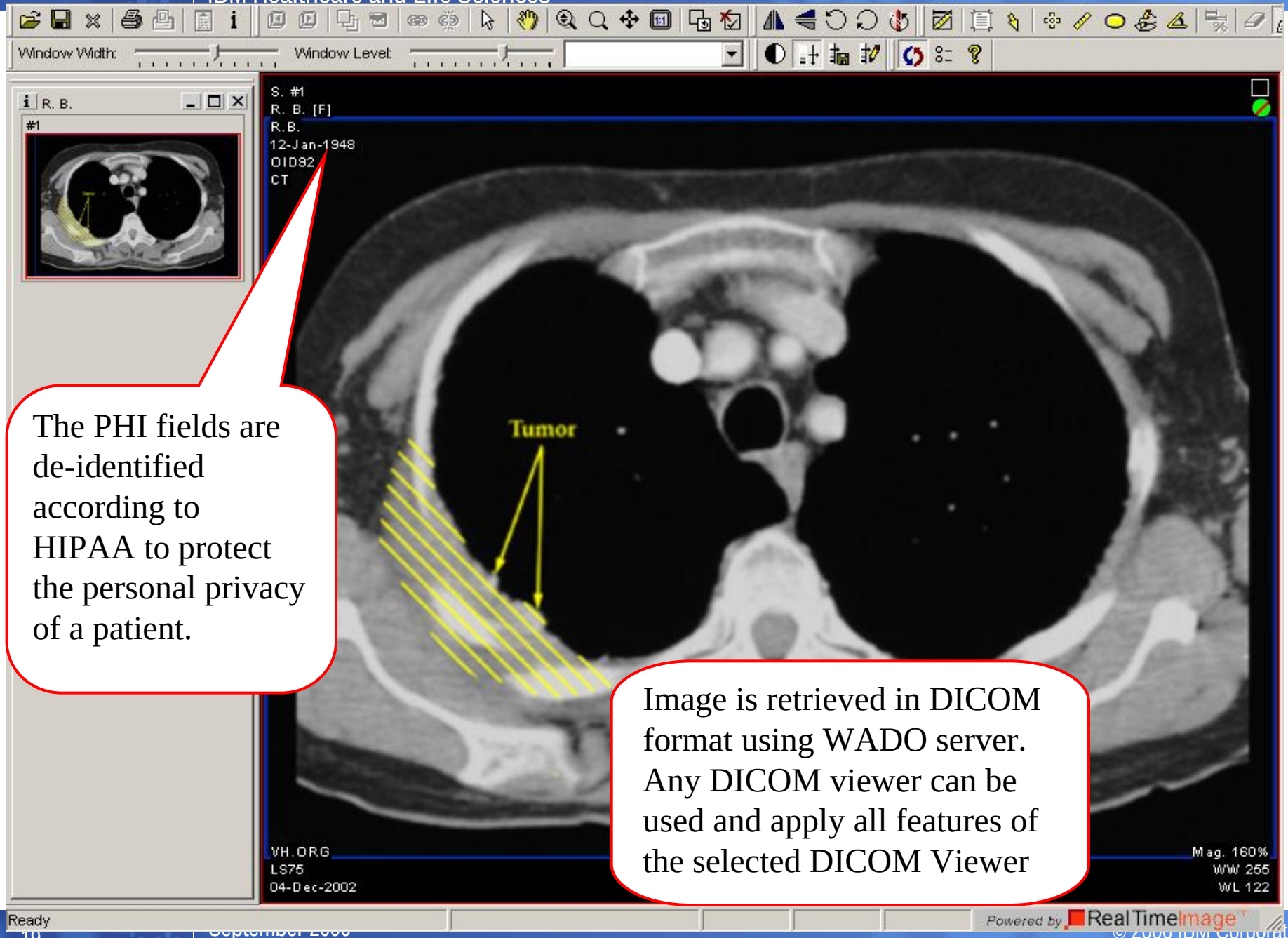


The PHI fields are de-identified according to HIPAA to protect the personal privacy of a patient.

Image is retrieved in DICOM format using WADO server. Any DICOM viewer can be used and apply all features of the selected DICOM Viewer


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# Browser Interface

- Portal-based interface
  - Personalized interface based on user role
- Query and browse stored data
  - Basic & Advanced Searches
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# Workflow and Collaboration

- Web-based portal interface
- Role-based security and access
  - Internal
  - External
- Workflow templates for common tasks
  - Send for QA/QC
  - Send for Analysis


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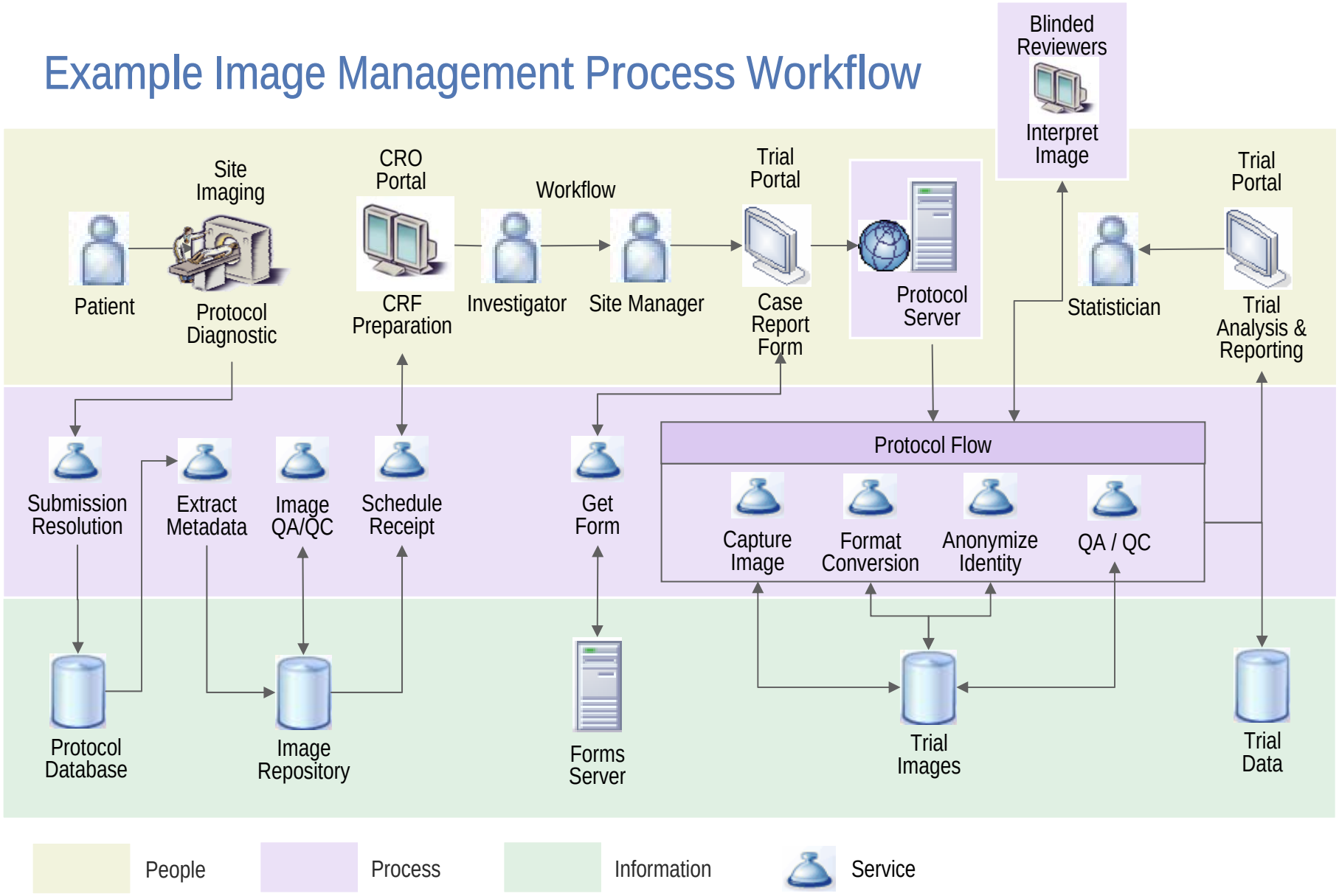
# Example Image Management Process Workflow





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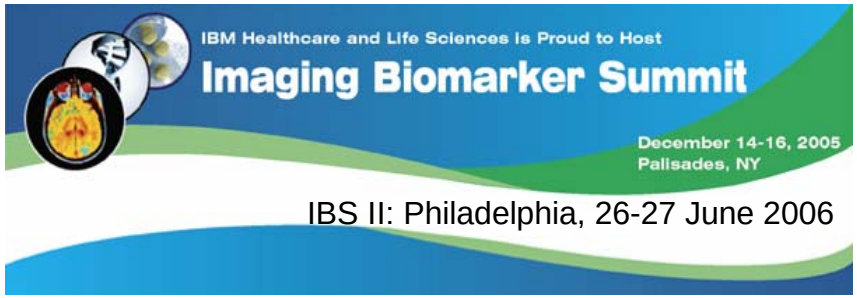
# IBM organized Imaging Biomarker Summits in December 2005 and June 2006

- The Imaging Biomarker Summits provided a Forum for the exchange of ideas and best practices related to Biomarker based Pharma R&D, with special emphasis on the impact of Imaging technologies. It was attended by over 70 representatives from Pharma, Biotech, Government & Academic Medical Research Centers, FDA, Medical Device Manufacturers and other IBM Partners.
- The Imaging Biomarker Summit featured presentations, facilitated Workshops, and a Panel Discussion led by Prof. Frank Douglas (MIT)
- Keynote presentations were be given by
  - Peter Corr, Pfizer R&D
  - Carol Kovac, IBM HC & LS
  - Gerd Schmitz, Danubian Biobank
  - George Mills, FDA
  - Larry Schwartz, MSK Cancer Center
- Presentations at IBS II were be given by
  - Andrew von Eschenbach, FDA
  - Pfizer, Genentech, Merck & FNIH
  - NCI, UCLA, JHU, Wash U, U MD
  - GE HC, Siemens, Philips
  - IBM, VirtualScopics, Kitware
- Discussions of Imaging Biomarkers in Oncology, Neurosciences, and Cardiovascular disease
- Workshops on
  - Imaging Biomarker Research / Discovery
  - Imaging Biomarkers in Pharma R&D
  - IT Standards and Architectures




IBS II: Philadelphia, 26-27 June 2006

Participating Organizations
IBS I: Pfizer, Merck, Novartis, J&J, Amgen, Roche, BMS, B-I, PhRMA, FDA, GE, Siemens, Philips, NCI, NIH, Yale, MSK, Scripps, UCLA, KI, Lyon, Danubian Biobank, iCapture ...
IBS II: FDA, Pfizer, Merck, J&J, Novartis, GSK, AZ, Wyeth, B-I, Astellas, Genentech, Amgen, BMS, PhRMA, NIH, NCI, NIBIB, NIST, GE, Siemens, Philips, UCLA, JHU, Wash U, U of MD, U of Texas...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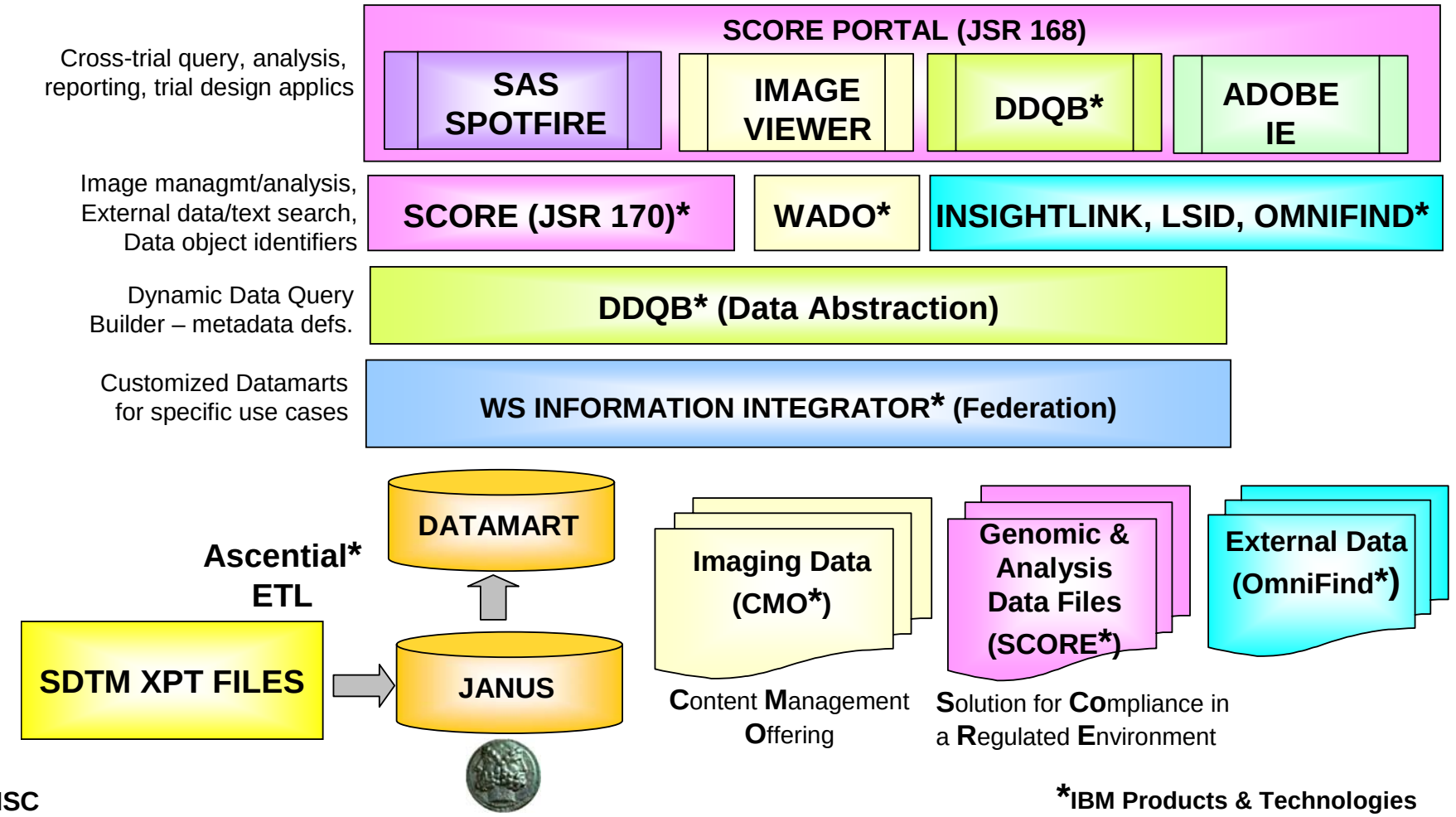
# For future drug submissions, Imaging Data should be integrated with other Data types and included in Data Models such as JANUS




**CDISC**
Clinical Data Interchange Standards Consortium

***IBM Products & Technologies**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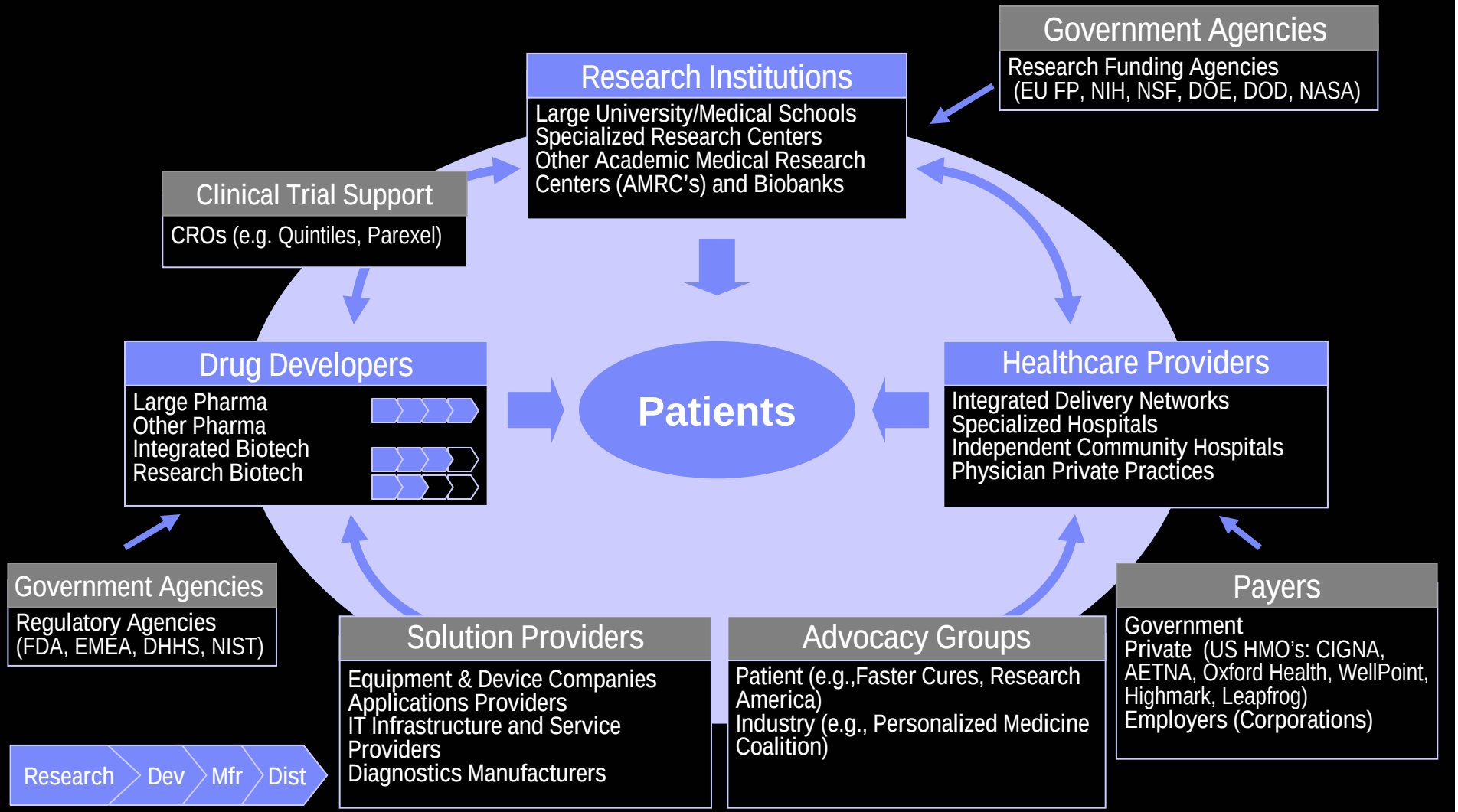
# The Role of Healthcare Stakeholders is to agree on Imaging Biomarker Strategies and Standards needed to move ahead



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